

### REMARKS/ARGUMENTS

Reconsideration of this patent application is respectfully requested in view of the foregoing amendments, and the following remarks. Claims 1-22 and 25-34 are in the application. Claim 1 has been amended. No new matter has been added.

The Examiner rejected claims 1-22 and 25-34 under 35 U.S.C. §112, second paragraph, for being indefinite. Applicant has amended claim 1 to recite "establishing and identifying . . ." in step g according to the Examiner's suggestion, and to further clarify the invention.

The Examiner rejected claims 1-35 under 35 U.S.C. §112, first paragraph, for being non-enabled. Applicant respectfully traverses.

Applicant has amended step a) of claim 1 to recite that the combination has in common at least three fluorochrome conjugated monoclonal antibodies that are specific for tumor cells of interest contained in said neoplastic samples.

An example of such combination of markers is described in

the specification in the paragraph bridging pages 23 and 24 for the identification of mature tumour B-cells.

In the last paragraph on page 4 of the specification, it states that "in the last decade, many different reports have been published which show that neoplastic cells from a great majority of patients suffering from haematological malignancies display aberrant patterns of antigen expression as detected through the use of several triple and quadruple combinations of monoclonal antibodies analyzed by flow cytometry (Reviewed in Vidriales et al, Best Clin Res Pract, 2003; 16: 599-612)". In addition, "based on these abnormalities, several disease-type specific panels of three and four colour combinations of monoclonal antibody reagents have been proposed for the systematic identification of leukemic cells expressing aberrant phenotypes, in virtually every patient with precursor B-Acute lymphoblastic leukemia (ALL; Lucio et al, Leukemia, 2001; 15: 1185-1192), T-ALL (Porwit-MacDonald, Leukemia, 2000; 14: 816-825), acute myeloblastic leukemia (AML; San Miguel et al, Blood, 2001; 98: 1746-1751), B-cell chronic lymphocytic leukemia (Rawstron et al., Blood 2001; 98: 29-35) and other B-cell chronic lymphoproliferative disorders (Sanchez et al, Leukemia, 2002; 16: 1460-1469), among other diseases". This

means that any of these panels could be used just by adding in each panel of combinations of monoclonal antibodies at least three of the monoclonal antibodies (specific for the identification of tumor cells in neoplastic samples) in the panel in common in every combination in the panel.

The Examiner also stated that the claims are only directed to measurement of fluorescence emissions, but that at least two measurements of light scatter and at least four measures of fluorescence emissions are taken. Applicant has amended step b) of claim 1 to recite "sequentially measuring light scatter and the fluorescence emissions . . . .".

The Examiner also stated that the breadth of the claims does not specifically state how phenotypic aberrations can be established and defined without undue experimentation.

Applicant has amended paragraph f) of claim 1 to recite:

"sequentially identifying in the data files containing measurement information about the cells present in the neoplastic sample and merged as described in step d), those events corresponding to neoplastic cells as those populations of events

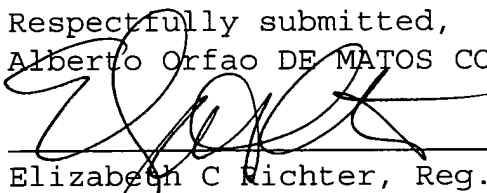
contained in the neoplastic sample which fall into the empty spaces identified in the multidimensional space generated by the flow cytometric measurements of light scatter and fluorescence emissions from pre-established standards in step e".

Support for this amendment can be found in the specification on p. 18, second paragraph: "...the neoplastic cells present in this new merged data file are identified using software tools, as those populations of at least 15 events falling into the spaces that remain empty in the initial file containing information on the cells of the normal/reactive samples..."

Accordingly, Applicant submits that the amended claims are in compliance with 35 USC §112. Early allowance is respectfully requested.

Respectfully submitted,  
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